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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/024,143 | 12/21/2001 | John S. Bobo | 108774 | 5486 |

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HUTCHISON & MASON PLLC
PO BOX 31686
RALEIGH, NC 27612

EXAMINER

VANIK, DAVID L

ART UNIT PAPER NUMBER

1615

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,143

Applicant(s)

BOBO ET AL.

Examiner

David L. Vanik

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the response to Election/Restriction filed on 4/29/2005. As acknowledged by applicants on 4/29/2005, claims 1-23 are pending in the instant application. It should be noted that this case was transferred from examiner Jyothsna Venkat to examiner David Vanik.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2 (part), 3(part), 4-7, and 23 (part) drawn to a composition comprising a chemical structure were in **R'X is an amino acid residue**, classified in classes 536, 554-544, subclass 1+ depending on the nature of the amino acid and substituent R.
 - II. Claims 1-2(part), 3(part), (8 (part) and 9-12, 23(part) drawn to a composition comprising chemical moiety wherein **R'X is a payload which a therapeutic agent**, classified in class 514, subclass 1+ depending on the nature of the therapeutic agent.
 - III. Claims 1-2(part), 3(part), and 13-16, 23(part) drawn to a composition comprising chemical moiety wherein structure **R'X is a payload which an imaging agent**, classified in class 514, subclass 1+ depending on the nature of the imaging agent.
 - IV. Claims 1-2(part), 3(part), and 17-22, 23(part) drawn to a composition comprising a chemical moiety wherein structure **R'X is a payload which**

is a targeting moiety classified in class 514, subclass 1+ depending on the nature of the imaging agent.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group I is drawn to composition, which has an amino acid, which is distinct and separate from group II that has a therapeutic agent. Both the groups have different modes of operation, different functions and different effects. Art anticipating or rendering obvious group I would not anticipate or render obvious group II.
3. Inventions I, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group I is drawn to composition, which has an amino acid, which is distinct and separate from group III that has an imaging agent. Both the groups have different modes of operation, different functions and different effects. Art anticipating or rendering obvious group I would not anticipate or render obvious group III.
4. Inventions I, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group I is drawn to composition, which has an amino acid, which is

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distinct and separate from group IV that has a targeting moiety. Both the groups have different modes of operation, different functions and different effects. Art anticipating or rendering obvious group I would not anticipate or render obvious group IV.

5. Inventions II, and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group II is drawn to composition, which has therapeutic agent, which is distinct and separate from group III that has an imaging agent. Both the groups have different modes of operation, different functions and different effects. Art anticipating or rendering obvious group II would not anticipate or render obvious group III.

6. Inventions II, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group II is drawn to composition, which has therapeutic agent, which is distinct and separate from group IV that has a targeting moiety. Both the groups have different modes of operation, different functions and different effects. Art anticipating or rendering obvious group II would not anticipate or render obvious group IV.

7. Inventions III, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group III is drawn to composition, which has an imaging agent, which is distinct and separate from group IV that has a targeting moiety. Both the groups have

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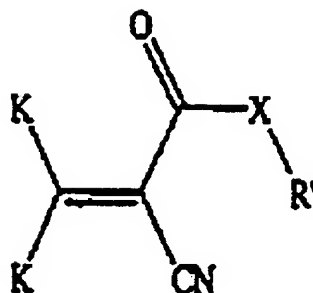
different modes of operation, different functions and different effects. Art anticipating or rendering obvious group III would not anticipate or render obvious group IV.

8. It is a search burden to examine all the groups since there is no common structure core present. Note that the simplest structure shown in claim I has many structures depending on the nature R' which is an organic residue. Not all the organic residues have common structure or in other words there is no special technical feature common to all the monomers. All the groups are drawn to distinct and separate inventions.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

10. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II, III, and IV, restriction for examination purposes as indicated is proper.

11. **In the event that applicant elects Groups I, II, III, or IV, the following election of species is required.** This application contains claims directed to the following patentably distinct substituent groups X, n, R, and R' with respect to the compound of **Claim 1**. It is requested that Applicant choose substituent groups relating to X, n, R, and R' from the following:



X is O, NR, S or Se;

R is absent, -H, $-(CH_2)_n$ alkyl, $-(CH_2)_n$ alkenyl, $-(CH_2)_n$ alkynyl, $-(CH_2)_n$ cycloalkyl, $-(CH_2)_n$ heterocyclyl, $-(CH_2)_n$ aryl or $-(CH_2)_n$ heteroaryl;

n is an integer from 0 to 10;

R' is a substituted organic residue; and

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

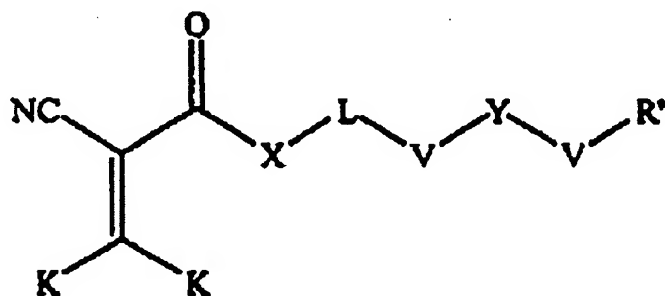
Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. In the event that applicant elects Groups I, II, III, or IV, the following election of species is required. This application contains claims directed to the following patentably distinct substituent groups X, n, R, R', R'', L, p, Y, and V with respect to the compound of **Claim 2**. It is requested that Applicant choose substituent groups relating to X, n, R, R', R'', L, p, Y, and V from the following:



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X is O, NR, S or Se;

R, independently for each occurrence, is -H, $-(CH_2)_n$ alkyl, $-(CH_2)_n$ alkenyl, $-(CH_2)_n$ alkynyl, $-(CH_2)_n$ cycloalkyl, $-(CH_2)_n$ heterocyclyl, $-(CH_2)_n$ aryl or $-(CH_2)_n$ heteroaryl;
n, independently for each occurrence, is an integer from 0 to 10;

R" is a substituted organic residue;

L is absent or is $-(CH_2)_n$ alkyl, $-(CH_2)_n$ alkenyl-, $-(CH_2)_n$ alkynyl-, $-(CH_2)_nO(CH_2)_p$ -, $-(CH_2)_nNR(CH_2)_p$ -, $-(CH_2)_nS(CH_2)_p$ -, $-(CH_2)_n$ alkyl $(CH_2)_p$ -, $-(CH_2)_n$ alkenyl $(CH_2)_p$ -, $-(CH_2)_n$ alkynyl $(CH_2)_p$ -, $-O(CH_2)_n$ -, $-NR(CH_2)_n$ -, or $-S(CH_2)_n$;

p is an integer from 0 to 10;

Y is absent or is C=O, SO₂, SO or C=S;

V, independently for each occurrence, is absent or is NR, O, S or Se; and

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 2 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

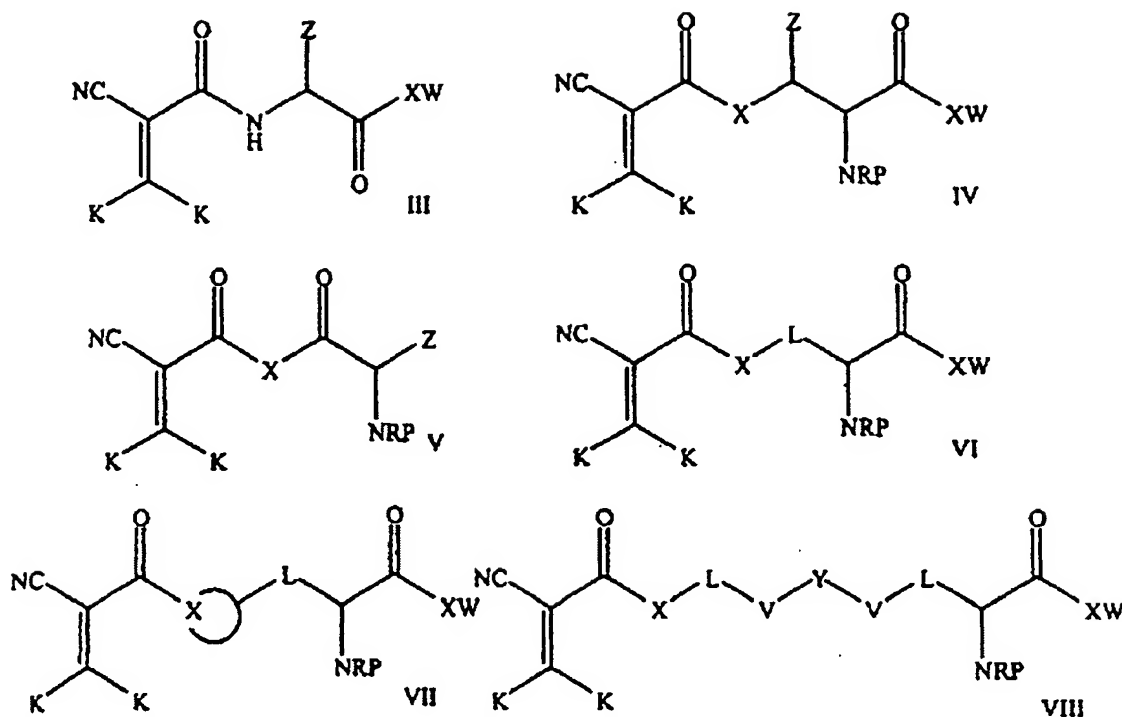
Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

13. In the event that applicant elects Groups I, II, III, or IV, the following election of species is required. This application contains claims directed to the following patentably distinct compounds chosen from the following group:



This application also contains claims directed to the following patentably substituent groups X, n, R, R', R'', L, p, Y, or V, P, W, and Z with respect to the compound of **Claim 3**. It is requested that Applicant choose substituent groups relating to X, n, R, R', R'', L, p, Y, or V, P, W, and Z from the following:

X, independently for each occurrence, is O, NR, S, or Se;

R, independently for each occurrence, is -H, $-(CH_2)_n$ alkyl, $-(CH_2)_n$ alkenyl, $-(CH_2)_n$ alkynyl, $-(CH_2)_n$ cycloalkyl, $-(CH_2)_n$ heterocyclyl, $-(CH_2)_n$ aryl or $-(CH_2)_n$ heteroaryl;

n, independently for each occurrence, is an integer from 0 to 10;

L, independently for each occurrence, is absent or represents $-(CH_2)_n$ alkyl-, $-(CH_2)_n$ alkenyl-, $-(CH_2)_n$ alkynyl-, $-(CH_2)_nO(CH_2)_p$ -, $-(CH_2)_nNR(CH_2)_p$ -, $-(CH_2)_nS(CH_2)_p$ -, $-(CH_2)_nalkyl(CH_2)_p$ -, $-(CH_2)_nalkenyl(CH_2)_p$ -, $-(CH_2)_nalkynyl(CH_2)_p$ -, $-O(CH_2)_n$ -, $-NR(CH_2)_n$ -, or $-S(CH_2)_n$;

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p, independently for each occurrence, is an integer from 0 to 10;

Y is absent or is C=O, SO₂, SO or C=S;

V, independently for each occurrence, is absent or is NR, O, S or Se;

P, independently for each occurrence, is H, lower alkyl or a nitrogen-protecting group;

W, independently for each occurrence, is -(CH₂)_nalkyl, -(CH₂)_nalkenyl, -(CH₂)_nalkynyl, -(CH₂)_ncycloalkyl, -(CH₂)_nheterocyclyl, -(CH₂)_naryl or -(CH₂)_nheteroaryl, one or more amino acid residues, or a payload; and

Z, independently for each occurrence, is -H or a substituted or unsubstituted alkyl, alkenyl, alkynyl, cycloalkyl, aralkyl, aryl, or heterocyclyl.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

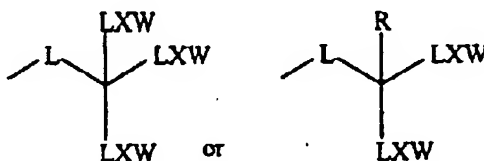
Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the

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species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. In the event that applicant elects the compound of Claim 23 as the R' group, the following further election of species is required. This application contains claims directed to the following patentably distinct substituent groups L, p, or W with respect to the compound of Claim 23. It is requested that Applicant choose substituent groups relating to L, p, and W from the following:



L, independently for each occurrence, is absent or is $-(CH_2)_n$ alkyl-, $-(CH_2)_n$ alkenyl-, $-(CH_2)_n$ alkynyl-, $-(CH_2)_nO(CH_2)_p$ -, $-(CH_2)_nNR(CH_2)_p$ -, $-(CH_2)_nS(CH_2)_p$ -, $-(CH_2)_n$ alkyl $(CH_2)_p$ -, $-(CH_2)_n$ alkenyl $(CH_2)_p$ -, $-(CH_2)_n$ alkynyl $(CH_2)_p$ -, $-O(CH_2)_n$ -, $-NR(CH_2)_n$ -, or $-S(CH_2)_n$;

p, independently for each occurrence, is an integer from 0 to 10; and

W, independently for each occurrence, is $-(CH_2)_n$ alkyl, $-(CH_2)_n$ alkenyl, $-(CH_2)_n$ alkynyl, $-(CH_2)_n$ cycloalkyl, $-(CH_2)_n$ heterocyclyl, $-(CH_2)_n$ aryl or $-(CH_2)_n$ heteroaryl, one or more amino acid residues, or a payload.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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15. Applicant's agent, Joshua Elliott, was contacted at telephone number (919) 829-9600 concerning this election requirement. Mr. Elliott was informed that, due to the complexity of the action, the reaction was submitted in writing.

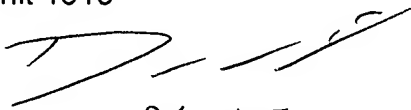
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

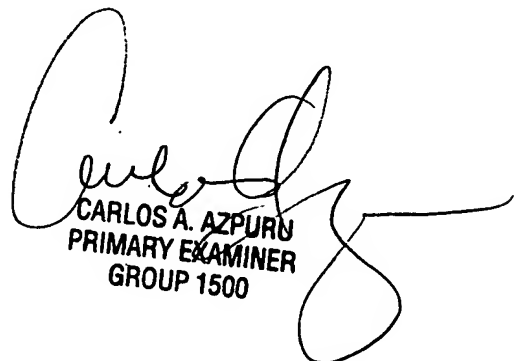
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615



9/2/05



CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500